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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,832	10/03/2006	**Kazunosuke Aida**	27562U	2366

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NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,832	AIDA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *11,13,14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12, and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed February 20, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:

a. Claims 1-10 have been amended.

b. Claims 11-16 has been added.

2. Claims 11, 13-14, and 16 are withdrawn from examination being drawn to the non-elected invention due to original presentation. Details are enclosed in the body of the office action.

3. Claims 1-16 are pending in the case.

4. Claims 1-10, 12, 15-16 are present for examination.

5. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

6. All grounds not addressed in the action are either moot or withdrawn.

7. New grounds of rejection are set forth in the current office action.

Election/Restrictions

6. Newly submitted claims 11, 13-14, and 16 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are drawn to at least one co-polymerizing monomer selected from the group consisting hydroxyethyl (meth)acrylate, (meth)acrylic acid, (meth)acrylic acid alkyl esters with C1-7 alkyl groups, and (meth)acrylic acid alkyl esters with C9-12 alkyl groups. The claims in the original presentation were solely

drawn to second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group. The newly added claims would have been subject to an election of species if originally presented due to the lack of common core between the monomers listed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11, 13-14, and 16 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-10, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-10, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter/written description rejection to the newly amended claims 1-10 and newly added claims 12, and 15. Claims 1-10, 12, and 15 now draw to a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate *and* N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group. There is support for a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate *or* N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group on Page 2, paragraph 7, Page 3, paragraph 8, and Page 8, paragraph 28-Table 1, among others in the specification but there is no support for a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate *and*N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group in the specification. Applicant cites Examples 1-4 as areas of support. Examples 1-3 have vinyl acetate but not PVP, Example 4 has PVP but not vinyl acetate. The examples do not support the amendments and the claims as written.

Claims 1-10, 12, and 15 are thereby rejected on the grounds of new matter and written description.

Claim Rejections - 35 USC § 103

Claims 1-10, 12, and 15 currently stand rejected on the grounds of new matter and

written description. However, the claims as written in their current form are subject to the following art rejections:

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al. (WO 02/069942) in view of Liedtke (DE 3811564).

It is noted that U.S. Pat. Publication 2004/0096491 will be used as the translation for Tateishi et al. (WO 02/069942). All references will relate to the translation.

It is noted that there is machine translation from the EPO website for Liedtke (DE 3811564). All references will relate to the translation.

Tateishi et al. teaches a transdermal patch comprising a support, an acrylic adhesive layer, and a release paper. The support has a preferred range of 5 to 1000 um and can be formed from different supports including polyethylene terephthalate.

The adhesive has an acrylic base preferably containing at least one selected from the group consisting of a block copolymer of a polymethyl methacrylate and a polyacrylate containing at least one selected from the group consisting of 2-ethylhexyl acrylate, butyl acrylate, diacetone acrylamide, or tetraethylene glycol dimethacrylate; a 2-ethylhexyl acrylate.N-vinyl-2-pyrrolidone.1,6-hexane glycol dimethacrylate copolymer; an aminoalkylmethacrylate copolymer E; and a 2-ethylhexyl acrylate.vinyl acetate copolymer; and more preferably at least one selected from the group consisting of a

2-ethylhexyl acrylate-N-vinyl-2-pyrrolidone 1,6-hexane glycol dimethacrylate copolymer and a 2-ethylhexyl acrylate.vinyl acetate copolymer. 2-ethylhexyl acrylate-N-vinyl-2-pyrrolidone.1,6-hexane glycol dimethacrylate copolymer and/or 2-ethylhexyl acrylate.vinyl acetate copolymer are preferred since they enhance both the skin permeability of the drug and preparation properties. These adhesives are commercially available and examples are DURO-TAK87-2097 and DURO-TAK87-4098. It is noted that while Tateishi does not specifically recite the typical ranges for the monomers in the adhesive Tateishi addresses that there are no specific restriction on the content of the acrylic polymer in the invention and many of the adhesives used for this purpose are commercially available such DURO-TAK87-2097 and DURO-TAK87-4098 which are utilized in Tateishi and in the instant specification (see Example 1) as a pressure sensitive adhesive. As the components utilized are the same, the monomer mixture would be expected to be the same in both the art and the instant application.

Tateishi also teaches that additional components including a 2-ethylhexyl acrylate.vinyl acetate copolymer can be incorporated into the adhesive. The adhesive can also include a plasticizer. It is noted that the term “obtained by” in claims 1-10 denotes a product by process limitation in which only the end product is the limitation for examination. The release paper can be from several materials including polyethylene terephthalate.

Tateishi et al. teaches several specific examples of transdermal patches with the drug pergolide mesylate, DURO-TAK87-4098, plasticizer, and polyethylene terephthalate as the support and the release layer. (Abstract, Page 1, paragraph 12,

Page 2, paragraph 14-15 and 20-25, Page 3, paragraph 32-34, Page 5, paragraph 41, Page 6, paragraph 52-53, Page 7, Example 3, paragraph 86-96, Example 4-1, paragraph 98-107).

Tateishi et al. does not expressly teach the incorporation of a cover material or the specific thickness of 12-30um.

Liedtke teaches the improved absorption of medicinal plasters form with an elastic foam/polymer barrier with polyethylene, an acrylic adhesive, a flexible barrier from polyethylene, a drug containing layer with a glue layer and the release foil. The advantages of encasing the plaster and having the plaster supported with a foam pad are increased variation, technical simplification, increased durability due to the elasticity and soft consistency, improved contour attachment to the skin surface, and reduced pressure on the skin. This also has improved duration of storage, improved adhesion and better sealing. (Abstract, Paragraph 1, 4-6, 9-11).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the foamed polymer, cover layer, and adhesive, as suggested by Liedtke, and produce the instant invention. The increased stability, storage, skin attachment, and durability would be substantial improvements that would create better drug profiles and reduced peeling of the transdermal patch. It would be obvious to also use the same adhesive for the outer layer (e.g. DURO-TAK) as used in the patch taught in Tateishi for simplified production, reduced costs, (no need to produce an additional adhesive), compatibility, and is an acrylate base.

One of ordinary skill in the art would have been motivated to do this because improved patient compliance through better skin attachment and durability is desirable. Increased storage periods are also very desirable for manufacturers as it lower production costs.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to arrive at the thickness of 12-30 um utilizing routine optimization within the ranges taught by Tateishi and produce the instant invention.

It is obvious to vary and/or optimize the thickness provided in the transdermal position, according to the guidance provided by Tateishi, to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

One of ordinary skill in the art would have been motivated to do this because it is desirable to adjust the components in a transdermal system to maximize the best possible drug delivery profile and thereby increase market share.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the

teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 1-2, 4-7, 9-10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arth et al. (U.S.Pat. No. 6461636) in view of Terahara et al. (WO 03/013611).

It is noted that U.S. Pat. Publication 2004/0241240 will be used as the translation for Terahara et al. (WO 03/013611). All references will relate to the translation.

Arth et al. teaches a transdermal therapeutic system (TTS) for pergolide and its salts, preferably mesylate. Examples 1-4 are drawn to pergolide mesilate in a TTS comprising a polyester release foil, a matrix mass comprising pergolide mesiliate, a 20um polyester support, a contact adhesive based on crosslinked acrylate copolymers, and then an outer cover of polyurethane encompassing the entire patch to the release film. The adhesives exemplified are of the Euradgit series comprising at least one copolymer of methacrylic acid, acrylic acid, their esters, and variations thereof (Abstract, Col.2, lines 20-38, Col. 5, lines 35-40, Col. 6, Examples 1-4, lines 45-68, Col. 7, lines 1-44).

Arth et al. does not expressly teach the use of a methacrylic C8 acid ester with vinyl acetate or N-vinyl-2-pyrrolidone or a plasticizer.

Terahara et al. teaches that acrylic adhesives acrylate.vinyl acetate copolymers, 2-ethylhexyl acrylate.2-ethylhexylmetjacrylate.dodecyl methacrylate, and methyl acrylate.2-ethylhexyl acrylate copolymer are available commercially as the DURO-TAK acrylic series, Eudragit series, and TSR containing N-vinyl-2-pyrrolidone (such as 2-ethyldexyl acrylate.vinylpyrrolidone copolymer solution with1,6-hexaneglycol dimethyacrylate and are analogous and can be combined. Terahara also teaches the inclusion of plasticizers in the adhesive and that support layers can be composed of several material including polyurethane, polyethylene, and polyethylene terephthalate (Page 2, paragraph 28-37, Page 3, paragraph 38-42). While Terahara does not teach the specific monomer mixture of 2-ethylhexyl acrylate-N-vinyl-2-pyrrolidone 1,6-hexane glycol dimethacrylate, 2-ethylhexyl acrylate.vinyl acetate copolymer. 2-ethylhexyl acrylate-N-vinyl-2-pyrrolidone.1,6-hexane glycol dimethacrylate copolymer, he teaches that these adhesives are commercially available through the DURO-TAK acrylic adhesive series, and Eudragit ® series. As DURO-TAK87-4098 which is utilized in the instant specification (see Example 1) as a pressure sensitive adhesive and commercially available, the components are the same absent any evidence to the contrary. It is well within the prevue of one in the art to choose any commercial adhesive with the desired properties for the final product.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute analogous materials and include plasticizers, as suggested by Terahara, and produce the instant invention. It would have been obvious to one of skill in the art to try the analogous materials taught, as there are only

two other commercial adhesives (DURO-TAK and TSR), that are analogous to Eudragit, and six other support materials other than polyurethane. It is well within the prevue of one in the art to choose any commercial adhesive with the desired properties for the final product. One would add plasticizers, as they are known to improve skin irritation and removal.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have analogous choices to substitute the adhesives and support materials when motivated by pricing, availability, or desired properties of the in the final product. It is also desirable for manufacturers to add plasticizers as a reduction in skin irritation and improved removal are desirable qualities for patient preference and increasing marketshare.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arth et al. (U.S.Pat. No. 6461636) in view of Terahara et al. (WO 03/013611) as in claims 1-2, 4-7, 9-10, and further in view of Liedtke (DE 3811564).

The teachings of Arth et al. and Terahara et al. are discussed above.

Arth in view of Terahara does not expressly teach the use of foamed polymers.

Liedtke teaches the improved absorption of medicinal plasters with an elastic foam/polymer barrier with polyethylene, an acrylic adhesive, a flexible barrier from polyethylene, a drug containing layer with a glue layer and the release foil. The design construction is similar to the one taught by Arth except for the foamed polymer. The advantages of encasing the plaster and having the plaster supported with a foam pad is increased variation, is technically simpler, and increased durability due to the elasticity and soft consistency, improved contour attachment to the skin surface, and reduced pressure on the skin. This also has improved duration of storage, improved adhesion and better sealing. (Abstract, Paragraph 1, 4-6, 9-11).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the foamed polymer as suggested by Liedtke, and produce the instant invention. The increased stability, storage, skin attachment, and durability would be substantial improvements that would create better drug profiles and reduced peeling of the transdermal patch.

One of ordinary skill in the art would have been motivated to do this because improved patient compliance through better skin attachment and durability is desirable. Increased storage periods are also very desirable for manufacturers as it lower production costs.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the

teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

14. Applicant's arguments filed February 20, 2008 have been fully considered but they are not persuasive. Applicant asserts that Tateishi et al. (WO 02/069942) in view of Liedtke (DE 3811564) does not teach the combination of monomers, the support film thickness, and a cover. This is not persuasive as addressed above as Tateishi does teach the combination of monomers, a transdermal patch comprising a support, an acrylic adhesive layer, and a release paper wherein the support has a preferred range of 5 to 1000 um which can be routinely optimized by one of skill in the art, and Liedtke address the benefits of advantages of encasing the plaster with a foam pad including improved contour attachment to the skin surface which would include the sides of the patch taught in Tateishi as it covers the patch. The art meets the composition recitations of the claims.

Applicant's arguments with respect to Arth et al. (U.S.Pat. No. 6461636) in view of Terahara et al. (WO 03/013611)have been fully considered but they are not persuasive as Applicant's assertion that there is no motivation to modify where Terahara et al. teaches that DURO-TAK acrylic series, Eudragit series, and TSR containing N-vinyl-2-pyrrolidone (such as 2-ethyldexyl acrylate.vinylpyrrolidone

copolymer solution with1,6-hexaneglycol dimethyacrylate and are analogous and can be combined and are known in the art to be analogous is not persuasive as Terahara teaches that these adhesives are commercially available and it is well within the prevue of one in the art to choose any commercial adhesive with the desired properties for the final product particularly when motivated by pricing, availability, or desired properties of the in the final product.

The arguments with respect to the content of Arth et al. (U.S.Pat. No. 6461636) in view of Terahara et al. (WO 03/013611) and further in view of Liedtke (DE 3811564) on the issue of the cover material and the adhesive are addressed above.

Conclusion

15. Claims 1-10, 12, and 15 are rejected.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612